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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

COUNTS, GARY W

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/887,871

Applicant(s)

AMIRKHANIAN, VAROUJ

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Priority Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 32-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of the claims

The amendment filed September 18, 2002 is acknowledged and has been entered.

Election/Restrictions

1. Newly submitted claim is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claim 34 involves at the separation channel having a second width larger than the first width and a transition from the first width to the second width, the detection section defining a detection zone at a distance of 100 to 500 times the second width from the transition and means for axially detecting radiation emission from the detection zone. Claims 1 and 30 do not require these limitations.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 34 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 6 "close proximity" is vague and indefinite. It is unclear what is considered to be proximate". There is no definition of the recitation "close proximity" provided in the specification. See also deficiency found in claim 30.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 7, 26, 27, and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al (Axial-Beam Laser-Excited Fluorescence Detection in Capillary Electrophoresis, Anal. Chem. 1992, vol. 64, 1741-1744).

Taylor et al disclose a detection system for axial-beam laser excited fluorescence detection in capillary electrophoresis. Taylor et al disclose the use of a fiber optic which focuses the excitation laser beam which directs the light along the capillary rather than across it (col 1, page 1741, lines 1-27). Taylor et al also disclose that this fiber is directed into an end of the detection section in proximity to the detection zone (col 1, page 1742, lines 8-10). Taylor et al also disclose the use of cladding material and a jacket which surround the fiber for guiding the excitation radiation from the excitation source to the detection zone (col 2, page 1741, lines 12-18). Taylor et al

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also disclose a means for detecting radiation emission from the detection zone (col 1, page 1742, lines 22-39).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Liu et al (US Patent 5,416,879).

See above for teachings of Taylor et al.

Taylor et al differ from the instant invention in failing to teach the tube is made of Teflon and the light transmitting material comprises a gel.

Liu et al disclose Teflon fluoropolymer capillary tubing which has a refractive index in the range of approximately 1.29 to 1.31 (col 4, lines 18-21). This Teflon tubing allows for the channeling light through a light conducting core region which is surrounded or clad by the Teflon fluoropolymer which has a lower refractive index to the light than the material comprising the core and thus allows the propagation of light with negligible losses through an optical fiber (col 3, lines 50-55).

It would have been obvious to one of ordinary skill in the art to incorporate the use of the Teflon fluoropolymer as taught by Liu et al into the detection system of Taylor et al because Liu et al shows that this Teflon tubing allows for the channeling of light through a light conducting core region which is surrounded or clad by the Teflon

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fluoropolymer which has a lower refractive index to the light than the material comprising the core and thus allows the propagation of light with negligible losses through an optical fiber.

With respect to the light transmitting material comprising a gel Taylor et al teaches the insertion of the fiber (light transmitting material) into the separation channel (comprised of the gel), thus the light transmitting material comprises a gel.

4. Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Hazman et al (US Patent 5,625,403).

See above for teachings of Taylor et al.

Taylor et al differ from the instant invention in failing to teach introducing excitation radiation from at least two radiation sources providing radiation at different wavelengths. Taylor et al also fail to teach the use of a beam splitter.

Hazman et al disclose the use of multiple diode lasers (radiation sources), each of which emits a source beam of light of different wavelengths (see abstract). Hazman et al also disclose an optical element that channels the radiation from the different radiation sources. Hazman et al also disclose the use of a beam splitter (see figure 2). The use of the radiation sources, optical element and beam splitter provides a method of recording on an optically-sensitive medium and enables the realization of a practical high power optical head (col 2, lines 27-36).

It would have been obvious to one of ordinary skill in the art to incorporate the use of radiation sources, an optical element and a beam splitter as taught by Hazman et al into the detection system of Taylor et al because Hazman et al shows that the use of

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the radiation sources, optical element and beam splitter provides a method of recording on an optically-sensitive medium and enables the realization of a practical high power optical head.

5. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Hazman et al (US Patent 5,625,403 as applied to claims 1-5, 7, 9-14, and 29-31 above, and further in view of Amirkhanian et al (US Patent 6,184,990).

See above for teachings of Taylor et al in view of Hazman et al.

Taylor et al differ from the instant invention in failing to disclose a means of introducing excitation radiation comprising two fibers directed at the detection zone, wherein each fiber is coupled to one radiation source.

Amirkhanian et al disclose the use of two optical fibers that are utilized for delivery of the excitation from two or more different sources. This arrangement enables multiple fluorescence species in the same sample to be excited at the same time for simultaneous detection.

It would have been obvious to one of ordinary skill in the art to incorporate the use of two optical fibers as taught by Amirkhanian et al into the detection system of Taylor et al because Amirkhanian et al shows that this arrangement enables multiple fluorescence species in the same sample to be excited at the same time for simultaneous detection.

6. Claims 16, 17 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Zhu et al (US Patent 5,763,277).

See above for teachings of Taylor et al.

Taylor et al differ from the instant invention in failing to teach a means for axially detecting radiation emission from the detection zone.

Zhu et al disclose a detection system which comprises a capillary tube (col 6, line 46) used for electrophoresis (separation channel) (col 2, lines 49-51) which defines a detection zone. Zhu et al disclose that sample analyte fluorescence is caused to occur by the application of energy (excitation radiation) to sample analytes caused to be present within the system (col 1, lines 62-65, see also figure 1). Zhu et al disclose the use of an axially oriented fiber optic which is directed into an end of the detection section in proximity to the detection zone. Zhu et al disclose that this fiber optic transmits the produced fluorescence (radiation emission) to a detector system (col 3 lines 1-6, see also figure 1). Zhu et al also disclose that the inner diameter of the axially oriented system component is increased at the location of contained axially oriented fiber optic means (col 5, lines 1-3). The use of this fiber optic provides a system of use for inducing and detecting sample analyte(s) identifying fluorescence.

It would have been obvious to one of ordinary skill in the art to incorporate the use of a fiber as taught by Zhu et al (US Patent 5,763,277) into the detection system of Taylor et al because Zhu et al shows that the use of this fiber optic provides a system of use for inducing and detecting sample analyte(s) identifying fluorescence.

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Zhu et al (US Patent 5,763,277) as applied to claims 1-5, 7, 16, 17, 25-31 above, and further in view of Letcher et al (US Patent 6,326,213).

See above for teachings Taylor et al and Zhu et al.

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Taylor et al differ from the instant invention in failing to teach the means for axially detecting radiation emission shares the same single fiber as the means for introducing excitation radiation axially to transmit excitation radiation and radiation emission.

Letcher et al disclose a single step-tapered fiber used for excitation and detection (col 3, lines 1 and 2, see also abstract). The use of this fiber allows for enhancement of the sensitivity of a fiber-optic biosensor using fluorescent immunoassay techniques for the rapid detection of a pathogen.

It would have been obvious to one of ordinary skill in the art to incorporate the fiber of Letcher et al into the detection system of Taylor et al because Letcher et al shows that the use of this fiber allows for enhancement of the sensitivity of a fiber-optic biosensor using fluorescent immunoassay techniques for the rapid detection of a pathogen.

8. Claims 19-22, are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Zhu et al (5,763,277), and Letcher et al (US Patent 6,326,213) as applied to claims 1-5, 7, 16-18, and 25-31 above, and further in view of Hazman et al (US Patent 5,625,403).

See above for teachings of Taylor et al, and Zhu et al, and Letcher et al.

Taylor et al differ from the instant invention in failing to disclose a confocal optical element that transmits excitation radiation and radiation emission.

Hazman et al disclose the use of a dichroic beam combiner along with a set of lens. This dichroic beam combiner is used to selectively reflect and transmit light

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according to its wavelength (col 4, lines 30-33). The use of the beam combiner and set of lens allows for the combination of laser beams and enabling the realization of a practical high power optical head.

It would have been obvious to one of ordinary skill in the art to incorporate the beam combiner and set of lens as taught by Hazman et al into the detection system of Taylor et al because Hazman et al shows that the use of the beam combiner allows for selectivity of light reflection and transmission according to its wavelength and the beam combiner and set of lens also allows for the combination of laser beams and enabling the realization of a practical high power optical head.

9. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Pentoney, Jr. et al (US Patent 5,675,155).

See above for teachings of Taylor et al.

Taylor et al differ from the instant invention in failing to teach the use of a parabolic reflective collector.

Pentoney, Jr. et al (US Patent 5,675,155) disclose the use of a high collection efficiency parabolic reflector (col 5, lines 14-39). The use of this parabolic reflector allows for an economical highly sensitive, stable and rugged detection system for use in connection with high throughput separation systems and also allows for multiple excitation wavelengths and detecting multiple emission wavelengths using a single detector (col 2, lines 24-32).

It would have been obvious to one of ordinary skill in the art to incorporate the use of a parabolic reflector as taught by Pentoney, Jr. et al into the detection system of

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Taylor et al because Pentoney, Jr. et al shows that the use of this parabolic reflector allows for an economical highly sensitive, stable and rugged detection system for use in connection with high throughput separation systems and also allows for multiple excitation wavelengths and detecting multiple emission wavelengths using a single detector.

Double Patenting

10. Claims 1-31 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 09/887,953. Although the conflicting claims are not identical, they are not patentably distinct from each other because It would have been obvious to one of ordinary skill in the art to incorporate the radiation in certain directions in order to optimize the measurement of the signal.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

11. Applicant's arguments filed September 18, 2002 have been fully considered but they are not persuasive.

Applicant argues that the Taylor et al reference does not teach a system in which excitation radiation is introduced by an optic fiber having an end in close proximity to the detection zone. This is not found persuasive because the Taylor et al reference discloses the use of a fiber optic which focuses the excitation laser beam which directs the light along the capillary rather than across it (col 1, page 1741, lines 1-27). The

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Taylor et al reference disclose a 51um o.d. fiber optic directed into an end of the capillary in proximity to the detection zone (col 1, page 1742, lines 8-10). Because of the disclose of Taylor et al and by way of applicant's own disclosure on page 17 lines 6-7 of the specification. The detection zone is not necessarily a well-defined zone with well-defined boundaries and also because no definition is provided in the specification for the term "close proximity" it is the examiner's position that the Taylor et al reference reads on the claims as recited.

Applicant argues that the Zhu et al reference does not make up for the deficiencies of the Taylor et al reference because Zhu et al is not directed to introducing excitation radiation to the detection zone. This is not found persuasive because examiner has not relied upon the Zhu et al reference for this limitation, but rather for the limitation of axially detecting radiation emission.

Applicant argues the provisional double patenting. Applicant asserts that the examiner has not provided sufficient basis to support his view that it would have been obvious to one of ordinary skill in the art to incorporate the radiation in certain directions in order to optimize the measurement of the signal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to rearrange the means for introducing excitation and means for detecting radiation emission to optimize the measurement of the signal. Further it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Conclusion

No claims are allowed.

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12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

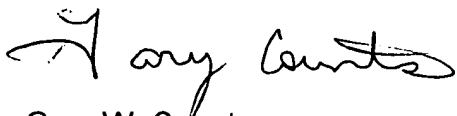
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Gary W. Counts

Examiner

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October 1, 2002



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10/01/02